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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,763	07/08/2003	Ung-Kil Jee	T10086	9902

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ALAN J. HOWARTH
P.O. BOX 1909
SANDY, UT 84091-1909

EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/615,763	JEE, UNG-KIL	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) *26-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/21/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group I, claims 1-25 is hereby acknowledged. Applicant gave no arguments to the Election/Restriction requirement; therefore, the election is made **without** traverse. Claims 1-25 are being examined on their merits herein, and claims 26-60 are being withdrawn from consideration because they do not read on the elected group. The election requirement is deemed proper and made FINAL.

Priority

This application claims priority to Republic of Korea application 10-2002-0061260 filed on 10/8/2002. Applicant's priority is acknowledged.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 8-9, 13-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (U.S. Patent 6,743,436) in view of Chen et al. (U.S. Patent 6,383,471).

Lee et al. teach an injectable anesthetic composition comprised of 1 to 2% by weight of the total composition of propofol (meeting the limitations of 1 and 15; Col. 4, lines 20-22). The composition further comprises SOLUTOL HS 15 (polyethylene glycol

660 hydroxystearate) in an amount of 0.1 to 10% of the total composition (further meeting the limitation of claim 1 and 16), egg lecithin in an amount of 0.1 to 5% of the total composition (meeting the limitations of claims 2-3, 8-9), ethanol and propylene glycol (meeting the limitations of claim 19; Col. 4, lines 36-48). A tonicity agent, such as glycerol is also added (meeting the limitation of claim 14; Col. 5, lines 38-40).

Lee et al. do not teach the injectable propofol composition further comprised of tetrahydrofurfuryl alcohol polyethyleneglycol ether, pH regulators, thickening agents, antioxidants, complexing agents, or antiseptics.

Chen et al. teach a pharmaceutical composition for the improved delivery of ionizable hydrophobic compounds (including propofol; Col. 7, line 11). The composition contains solubilizers, with tetrahydrofurfuryl alcohol PEG ether, glycerol, and propylene glycol being among those preferred (further meeting the limitation of claim 1 and 17; Col. 31, lines 54-57 and Col. 32, line 46-48). The composition further contains pH regulators, such as ascorbic acid and gluconic acid (meeting the limitation of claims 18 and 20; Col. 11, lines 9-54), thickening agents such as methylcellulose (further meeting the limitation of claim 18 and 21; Col. 32, line 31), sulfates (further meeting the limitation of claim 18 and 23; Col. 33, line 21), benzyl alcohol (meeting the limitation of claim 24; Col. 31, line 45) and phosphate (as sodium phosphate; meeting the limitation of claim 22; Col. 11, line 30).

Accordingly, it would be obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Lee et al., which teach an anesthetic composition for intravenous injection comprised of propofol, polyethylene glycol 660

hydroxystearate, egg lecithin, ethanol, propylene glycol and glycerol, with Chen et al. which teaches utilizing the ingredients tetrahydrofurfuryl alcohol PEG ether, pH regulators, thickening agents, complexing agents, antioxidants, and antiseptics for improved delivery of ionizable hydrophobic compounds. One would have been motivated to combine the teachings of Lee et al. with Chen et al. in order to formulate an injectable composition that is stable and clear, and with the addition of the tetrayhydrofurfuryl alcohol polyethylene glycol ether, provide a maximal concentration of propofol to be administered to a patient.

Claims 4-7, 10-12, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. and Chen et al. as applied to claims 1-3, 8-9, 13-24 above, and in further view of De Tommaso (PG Pub 2002/0107291).

Lee et al. and Chen et al. teach formulations comprised of propofol, polyethylene glycol 660 hydroxystearate, tetrahydrofurfuryl alcohol PEG ether, lecithin, a liquid excipient, a tonicity agent, pH regulators, thickening agents, complexing agents, antioxidants and antiseptics.

Lee et al. and Chen et al. do not teach formulations comprised of a bile salt or a mixture of a bile salt and lecithin.

De Tommaso also teach an injectable pharmaceutical composition comprised of propofol, in which a bile salt, including glycocholic acid, cholic acid, and taurocholic acid, is incorporated into the injectable formulation (meeting the limitation of claims 4-7, 12; Pg. 1, paragraph 0015). The composition is further comprised of lecithin, and the

formulation is prepared by adding lecithin to an aqueous solution of the bile salt (meeting the limitation of claims 10-11; Pg. 2, paragraph 0025, 0029).

It is obvious to vary and/or optimize the amount of bile salts provided in the composition, according to the guidance provided by De Tommaso to provide a composition having the desired properties such as the desired percentage weight of the bile salt for a more transparent injectable formulation. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Furthermore, it is obvious that because the components of the propofol composition of the prior art and the components of the present composition are the same, it is obvious that they will share the same physical properties, such as a transmittance at 660nm of greater than about 90%. Patent law states that "products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Accordingly, it would be obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Lee et al. and Chen which teach an anesthetic composition for intravenous injection comprised of propofol, polyethylene glycol 660 hydroxystearate, tetrahydrofurfuryl alcohol PEG ether, lecithin, a liquid

excipient, a tonicity agent, pH regulators, thickening agents, complexing agents, antioxidants and antiseptics, with De Tommaso et al. which teach an injectable composition comprised of propofol and bile salts. One having ordinary skill in the art would be motivated to combine the teachings of Lee et al. and Chen et al. with De Tommaso to provide an injectable anesthetic composition that is transparent and free of foreign particles inside the vial or bottle, which is important for product safety.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER